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REFEREE

E-filing

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFO\RNIA

RENEE CONTRATTO, on behalf of herself and the general public,

Plaintiff(s),

vs.

ETHICON, INC. et al., (dba GYNECARE WORLDWIDE), a New Jersey Corporation; JOHNSON & JOHNSON, a New Jersey Corporation; LIFECORE BIOMEDICAL, INC., a Florida Corporation; and DOES 1-25,

Defendant(s).

Case No.: C03-3804 MJJ (BZ)
JAMS REF. NO. 1100043994

REVISED SPECIAL MASTER'S ORDER #1: RE MOTIONS TO COMPEL PRODUCTION OF DOCUMENTS (Hrg. 4/11/05)

On April 11, 2005, various motions co compel production of documents presented by the parties were heard by Special Master Quinn. On May 4, 2005, the Special Master issued a Notice of Ruling. On May 16, 2005, the Special Master issued a draft of this Order to which defendants raised an issue as to the timing of their production (see ¶2.b below). This revised Order incorporates the Special Master's conclusions on that timing issue.

1. Plaintiff's Motion to Compel Production of MDDRP-Material

Plaintiff moved to compel production of documents withheld from production, and information redacted from documents, that were generated by Lifecore's attorneys in preparation for the proceedings regarding Intergel that took place before the Medical Devices Disputes Resolution Panel of the FDA. Plaintiff argued that the material was relevant to the issues of the safety and efficacy of Intergel, and that it was not subject to any work product protection. Defendants contended that the material withheld consisted of attorney work product that was entitled to protection because the MDDRP proceedings were an adversarial process akin to litigation.

FRCP 26(b)(3) protects as attorney work product materials prepared in anticipation of litigation or trial. This protection has been applied not only in actual civil and criminal litigation, but in a variety of administrative and other proceedings, such as arbitrations and patent proceedings, provided that they are "adversarial proceedings." *McCook Metals L.L.C. v. Alcoa, 192 F.R.D. 242 (N.D. Ill.)*, set forth the characteristics of an adversarial proceeding in the context of a patent appeal: (1) the patent applicant was in a defensive position and in an adversarial relationship to the patent examiner; (2) the attorney was required to draft intricate legal documents to persuade the examiner to make a finding favorable to the applicant; and (3) on appeal the applicant and the examiner were in a heightened adversary relationship since the examiner had ruled against the applicant.

The Special Master concludes that defendants have not demonstrated that the MDDRP proceedings exhibited these characteristics. First, the MDDRP was set up to give advice and make recommendations to the FDA about science issues, not to render a judgment on legal issues. (Plaintiff's Exh. 16, p. 4) The Panel's recommendation has no binding effect: the FDA may concur with it or reject it. The Panel considers "scientific disputes" which are defined to exclude "legal issues." Id. While Lifecore may have had an adversary relationship with the FDA after the agency issued a not approvable letter, it doesn't follow that the MDDRP

proceedings are adversarial. On the contrary, they are designed basically to provide a "second opinion" to the FDA in evaluating a medical device. Their fundamental purpose is to investigate and evaluate scientific claims, and provide neutral outside expert input to the agency. Second, there was no showing that Lifecore's lawyers acted in a litigation role. No evidence was presented that Lifecore's attorneys appeared before the MDDRP. Lifecore's attorney stated that she and her colleague drafted memoranda, evaluated experts, prepared presentations for the Panel and reviewed statistics. (Flannery decl. 11) There is no indication that they prepared pleadings or witnesses, or submitted any legal argument such as would be typical of lawsuits, arbitrations or patent proceedings. No doubt lawyerly skill went into the drafting of memoranda and presentations, but that is true of many documents that lawyers prepare in non-litigation contexts. Third, the MDDRP is not analogous to an appellate procedure in the patent application process. As stated, the MDDRP is not an appellate body – it could not reverse the FDA's adverse finding about Intergel.

For these reasons, the Special Master concludes that the documents withheld by Lifecore from production, or redacted, on the ground that they were prepared for the MDDRP proceeding are not entitled to work product protection, and accordingly should be produced.

2. Plaintiff's Motion to Compel Production of Documents Withheld or Redacted as Relating to the "Re-Launch" of Intergel

a. Production of Re-Launch Documents

Plaintiff's Request for Production No. 30 sought, "Any and all documents that refer, pertain, or relate to YOUR efforts at putting Intergel back on the market." Defendants have withheld and redacted documents that purport to deal with the consideration of whether to "re-launch" Intergel on the market. They represent that they have produced all documents dealing with the removal of Intergel from the market, but contend that "re-launch" materials are not relevant.

The Special Master perceives no distinction as to the relevance of the two categories of documents. Presumably, in considering both whether to stop marketing Intergel and whether to start marketing it again, defendants pondered, investigated and reached conclusions about the product's efficacy and safety. Both categories of documents are plainly relevant to issues in this case, and are likely to lead to the discovery of admissible evidence. Defendants have acknowledged there is no burden to producing these documents since the amount they withheld is "minuscule."

Accordingly, the Special Master overrules defendants' objections to RFP No. 30, and concludes that defendants are obligated to produce all responsive documents in this category that have been withheld, and to produce unredacted copies of documents that were previously produced.

b. Period of Time For Which Re-Launch Documents Are To Be Produced

After seeing a draft of this Order, defendants' counsel commendably brought to the Special Master's attention that they had previously limited their document productions (evidently with minor exceptions) to those documents generated prior to October 31, 2003. They take the position that documents generated after that date are not relevant. They asked whether they could employ such a cut-off date to the documents to be produced pursuant to this Order. Defendants note that October 2003 is over a year after plaintiff's surgeries, seven months after Intergel was withdrawn from market, after defendants completed their post-withdrawal investigation, and two months after this lawsuit was filed.

This query provoked plaintiff to object strenuously, and to protest that she had never before been aware that defendants were unilaterally employing a 10/31/03 cutoff to their productions. She argues that, in particular, documents pertaining to a possible "re-launch" of Intergel generated after 10/31/03 would be highly relevant. They should include, says plaintiff, internal documents about re-launch, and exchanges with the FDA about possible manufacturing

defects, among other things. Plaintiff also noted that two prior court orders required production of various categories of materials without any cutoff date.

The Special Master held a telephone hearing with counsel on this issue on May 17, 2005. Counsel represented that defendants' prior responses to document requests had objected to producing any documents generated after plaintiff's surgeries, but then stated that without waiving that objection they would produce documents responsive to the various requests. Their responses never specifically called out that 10/31/03 or any other date was being used as a cutoff.

Plaintiff made two requests: first, that defendants produce seven categories of documents relating to "re-launch"[1]; second, that defendants be ordered to supplement **all** their prior productions to include post 10/31/03 material. Defendants objected that plaintiff's seven categories represent an expansion of her prior document requests. Defendants also objected that production of post-10/31/03 materials would be unduly burdensome. However, they acknowledged that, to collect and produce **hard copy** post-10/31/03 documents in the seven "re-launch" categories would take about two weeks, and to produce **e-mail** for those categories would take another week to 10 days.

The Special Master concludes that, because defendants' discovery responses did not reasonably alert plaintiff's counsel that any cutoff was being imposed, plaintiff has not waived her right to seek post-10/31/03 material. The Special Master further concludes that defendants have not shown a basis for deeming all post-10/31/03 documents irrelevant. If defendants are pursuing the possibility of "re-launching" Intergel, or if defendants are continuing to communicate with the FDA about the safety or efficacy of Intergel or FeHA or about a re-launch of Intergel, such documents are potentially relevant. Third, the Special Master concludes that

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[1] (1) All documents reflecting communications between defendants or internal to a defendant post 10/31/03 regarding relaunch of Intergel or FeHA-related product; (2). All documents reflecting communications between any defendant and the FDA post 10/31/03 regarding the relaunch of Intergel or FeHA related-product; (3) All documents reflecting post 10/31/03 reanalysis by defendants of any old study for purposes of relaunch or any new study for purposes of relaunch; (4) All documents or communications between defendants and the FDA post 10/31/03 reflecting assistance to the FDA for the execution of any study for purposes of relaunch or analysis of the causes of post market adverse events: (5) All documents reflecting communications between defendants and outside consultants for purposes of relaunching Intergel or FeHA related product; (6) All documents reflecting Ethicon's decision not to proceed with the relaunch of Intergel or FeHA related product; (7) All documents reflecting any manufacturing or formula changes to Intergel for the purpose of relaunching Intergel or FeHA related product.

defendants are required to produce post 10/31/03 documents pertaining to "re-launch," both those described in plaintiff's prior document requests and in the seven categories. Any burden on defendants from having to produce documents other than those requested in prior document requests is amply justified by their failure to notify plaintiff that they were unilaterally imposing this cutoff. Fourth, the Special Master finds that plaintiff has not shown a basis at this time to require defendants to supplement their productions other than those pertaining to "re-launch" documents. Plaintiff may seek an order requiring supplementation of other categories of documents on a showing of good cause, and no undue burden on defendants.

3. Plaintiff's Motion to Compel Production of Documents Withheld or Redacted as Advertising and Marketing Material

Plaintiff's Request for Production Nos. 33, 55 and 56 sought documents relating the "marketing feedback for the extension tubes" and documents produced and deposition transcripts taken in a related California state court action (Contratto v Ethicon, el. al. (Alameda County Case No. RG04138391). Counsel represented that the state court documents involved advertising and marketing. It is unclear what, if any, deposition transcripts exist or to what they relate. In discussions among counsel, plaintiff has limited her request to advertising and marketing material used in California. In its 11/9/04 Order the court ordered defendants to produce files maintained by the supervisors of defendants' "sales and marketing." Notwithstanding that Order defendants evidently produced documents with redactions of all advertising and marketing information. Defendants contend that advertising and marketing materials are irrelevant because plaintiff cannot show that her doctor ever saw or relied on such materials in deciding to employ Intergel in connection with plaintiff's surgery. The record is still unclear as to what plaintiff's doctor relied on. It appears that she saw at least one advertisement for Intergel, and spoke to at least one sales representative about the product. But she did not testify clearly that she actually relied on any marketing or advertising material. Plaintiff argues that relevance does

not depend solely on her doctor's actual reliance, because such materials may demonstrate what claims defendants were making for their product and for what uses they recommended it.

The Special Master concludes that plaintiff has demonstrated sufficient relevance to permit discovery of this material. It is not possible now to know how plaintiff's doctor may testify with respect to her reliance on advertising. Also, advertising documents that made claims of the product's safety and efficacy or represented that it was suitable for off-label uses would be relevant to show that the use of the product on a patient such as plaintiff was something that defendants envisioned and encouraged. Moreover, any other finding would be inconsistent with Judge Zimmerman's ruling that company files maintained by sales and marketing supervisors should be produced. With respect to the state court deposition transcripts, there was no showing whether they contained material about marketing and advertising, but the Special Master cannot conceive of a reason why they should not be produced since, if they exist, they pertain to precisely the same dispute that exists in this federal action.

Accordingly, defendants' objections to RFP Nos. 33, 55 and 56 are overruled, and they shall produce all documents and material responsive to those requests.

4. Plaintiff's Motion to Compel Production of Foreign Regulatory Material

Plaintiff seeks documents relating to defendants' applications to foreign regulatory agencies for permission to market Intergel. Defendants object that their foreign applications are not relevant to this dispute since plaintiff's doctor plainly did not see or rely on them.

The Special Master concludes that plaintiff has not demonstrated a sufficient causal or logical relationship between compliance with foreign regulations and defendants' possible liability for the injuries to this plaintiff in California. Nor is there any showing that foreign regulation of Intergel and other devices is comparable to that in the United States. Defendants have offered persuasive evidence that production of this material would involve burden and expense that is likely to outweigh the probative value of the material in question.

Accordingly, the Special Master concludes that discovery of this material should not be required.

5. Plaintiff's Motion to Compel Production of Final Reports of Tests/Studies re FeHA

Plaintiff's RFP No. 26 sought final reports for any test, study or clinical trial for Intergel, FeHA and other products. RFP No. 27[B] sought all "e-mails, letters, memorandums, tests, studies, final reports, intermediary reports, laboratory notebooks, or protocols" for such tests and studies. Defendants have produced the final reports relating to Intergel, but objected to producing material for FeHA or any other compound or product. Plaintiff has limited her request on this motion to final reports and backup documents (as listed above) for FeHA only.

Plaintiff argues that FeHA, a compound of iron and hyuloranic acid, was a precursor product in the development if Intergel, which is composed of the same two ingredients. She provided declarations of two experts who opine that it is important for them to have available all reports, tests and documents concerning both Intergel and FeHA. One expert stated that, "there is very little difference between the precursor formulas for FeHA and Intergel." (Doody decl., 4) Defendants dispute that the compounds are substantially similar and criticize plaintiff's expert declarations as conclusory. But defendants offered no contrary evidence or expert opinion that FeHA is not substantially similar to Intergel.

The Special Master concludes that with respect to final reports of studies and tests plaintiff has shown a sufficient nexus between FeHA and Intergel to satisfy the relevance standard for discovery purposes. Defendants have not shown there is any burden or other reason not to require production. However, with respect to the types of back-up documents listed above that are requested in RFP 27[B], the Special Master is concerned (as was Judge Zimmerman) that the volume of such documents may exceed their usefulness. Plaintiff has not shown a sufficient basis, either in argument or expert declarations, to require defendants to produce every e-mail, lab report, notebook entry, etc. with respect to testing of FeHA.

Accordingly, with respect to RFP 26, defendants' objections to producing responsive documents relating to FeHA are overruled, and they shall produce all documents withheld on this basis, and unredacted copies of any documents previously produced in redacted form. With respect to RFP 27[B], plaintiff's motion is denied, without prejudice to their right to ask the court for leave to produce a reasonable number of specifically identified documents responsive to RFP 27[B].

6. Costs & Sanctions

The Special Master finds that plaintiff is the prevailing party on this motion, and that defendants were primarily responsible for the discovery dispute that this motion addresses. Accordingly, defendants shall pay 100% of the charges of JAMS for the Special Master to hear and decide this motion.

Plaintiff requests sanctions in the amount of $9,000 for attorneys' fees spent in bringing this motion. The Special Master has carefully considered this request, but on balance believes that defendants' objections – while largely unsuccessful -- had sufficient merit to justify requiring a judicial ruling.

ORDER

Good cause appearing, the Special Master ORDERS that:

1. Plaintiff's motion is GRANTED as stated above as to the documents relating to MDDRP proceedings, California-based advertising and marketing material, and final reports of FeHA studies tests and trials that are responsive to the document requests in question. Unless otherwise ordered, defendants may limit their production to documents created prior to October 31, 2003.

2. Plaintiff's motion is GRANTED as to re-launch documents responsive to Request No. 30 or to any of the seven categories of documents listed in Footnote 1 above. Such documents shall be produced regardless of when they were created.

3. Plaintiff's motion is DENIED as to foreign regulatory materials, backup materials regarding studies and tests of FeHA, and her request for sanctions.

4. In view of the time defendants have had since the May 4 Notice of Ruling to prepare to produce this material, except as to post-10/31/03 re-launch documents defendants shall commence production immediately of the documents as ordered herein and shall complete this production by Monday, May 23, 2005. Defendants shall produce all hard copy versions of post 10/31-03 re-launch documents by Friday, May 27, 2005, and shall produce all e-mail or other electronic forms of documents by Monday, June 6, 2005.

5. In the event defendants seek court review of any portion of this Order, they may withhold production of the documents pertaining to the issue to be reviewed. However, they shall produce the remaining documents as ordered above

6. Defendants shall pay 100% of the JAMS charges for the Special Master to hear and decide this motion.

Dated: May 19, 2005

Martin Quinn, Special Master